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Substitu	ite for form 1449A/	В/РТО		Complete If Known		
				Application Number	10/615,010-Conf. #8179	
INF	ORMATI	ON DIS	CLOSURE	Fillng Date	July 7, 2003	
STA	STATEMENT BY APPLICANT			First Named Inventor	Mladen Mercep, et al.	
				Art Unit	1642	
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	1	of	1	Attorney Docket Number	03818/100L651-US1	

	U.S. PATENT DOCUMENTS						
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where		
Initials*	No.	Number-Kind Code ² (If known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear		
Lp	AA .	US-2004/0033969-A1	02-19-2004	Burnet et al.			
ι_{r}	AB	US-2004/0005641-A1	01-08-2004	Burnet et al.			
4	AC	US-2001/0006962-A1	07-05-2001	Myhren et al.			

	FOREIGN PATENT DOCUMENTS							
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines,			
initiats*	No.1	Country Code ³ -Number ⁴ -Kind Code ³ (ii known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	₽		
6	BA	WO-97/41255	11-06-1997	Massachusetts Institute of Technology		Γ		
4	BB	WO-00/64882	11-02-2000	Glaxo Group Ltd.		╁		
4	BC	WO-99/64040	12-16-1999	Advanced Medicine Inc.		┢		
w	BD	WO-02/055531	07-18-2002	Pliva d.d.		厂		
5,	BE	WO-03/070254	08-28-2003	Sympore GMBH	1	\vdash		
5	BF	WO-03/070174-A2	08-28-2003	Sympore GMBH		 		
ζ,	BG	WO-03/070173-A2	08-28-2003	Sympore GMBH		┢┈		
ℓ_T	ВН	EP-0 283 055	09-21-1998	Pliva Pharm & Chem Works		H		
4	ВІ	EP-0 895 999	02-10-1999	Pfizer Products, Inc.				
نح	BJ		01-13-1999	Merck & Co., Inc.		H		

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·	NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				
4	CA	Burnet et al., "Conjugates of biologically active compounds, methods for their preparation and use, formulation, and pharmaceutical applications thereof," U.S. Provisional Application No. 60/357,789, filed February 15, 2002.					
<i>ل</i> خ	CB	Brandt-Rauf et al., "Fluorescent Assay For Estimating the Binding of Erythromycin Derivatives to Ribosomes," Antimicrobial Agents and Chemotherapy, American Society for Microbiology, Washington, D.C., 14(1):88-94. (1978).					

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Complete if Known Substitute for form 1449A/B/PTO Application Number 10/615,010 **INFORMATION DISCLOSURE** July 7, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Mladen MERCEP Art Unit TBA (Use as many sheets as necessary) **TBA** Examiner Name 03818/100L651-US1 3 Sheet of Attorney Docket Number

	U.S. PATENT DOCUMENTS						
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where		
Initials*	No.	Number-Kind Code ¹ (If known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear		
50	1.	4,474,768	10/02/1984	Bright			

	FOREIGN PATENT DOCUMENTS							
Examiner Cite Initials* No.1		Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶		
Si	2.	EP 0984019	03/08/2000	Pfizer Products Inc.				
5	3.	WO 98/56801	12/17/1998	Pfizer Products Inc.	· ·			

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4	4.	Gladue R. P. et al., "In Vitro and In Vivo Uptake of Azithromycin (CP-62,993) by Phagocytic Cells: Possible Mechanism of Delivery and Release at Sites of Infection," <i>Antimicrob. Agents and Chemother.</i> , 33. 1989, 277-282	
4	5.	Olsen K. M. et al., "Intrapulmonary Pharmacokinetics of Zithromycin in Healthy Volunteers Given Five Oral Doses," Antimicrob. Agents and Chemother., 40, 1996, 2582-2585	
4	6.	Mikasa, K. et al., "The anti-inflammatory effect of erythromycin in zymosan-induced peritonitis of mice," J. Antimicrob. Chemother., 30, 1992, 339-348	
(₂)	7.	"Discussion, Genomic organization of axolotl 1g genes," J. Immunol., 159, 1997, 3395-4005	
5	8.	Takizawa, H. et al., "Erythromycin Modulates IL-8 Expression in Normal and Inflamed Human Bronchial Epithelial Cells," Am. J. Respir. Crit. Care Med., 156, 1997, 266-271	
۲,	9.	Labro, M.T., "Anti-inflammatory activity of macrolides: a new therapeutic potential?" J. Antimicrob. Chemother. 41, 1998, 37-46	
5	10.	Denis A. et al., "Synthesis and Antibacterial Activity of HMR 36K47, A New Ketolide Highly Potent Against Erythromycin-Resistant and Susceptible Pathogens," Bioorg. & Med. Chem. Lett, 9, 1999, 3075-3080	
ιγ	11.	Agouridas C. et al., "Synthesis and Antibacterial Activity of Ketolides (6-O-Methyl-3-oxoerythromycin Derivatives): A New Class of Antibacterials Highly Potent against Macrolide-Resistant and -Susceptible Respiratory Pathogens," J. Med. Chem., 41, 1998, 4080-4100	
41	12.	Sun, Or Y. et al. J. Med. Chem. 2000, 43, 1045-1049	
4	13.	Denis A. et al., *Synthesis of 6-O-Methyl-Azithromycin and Its Ketolide Analogue via Beckmann Rearrangement of 9(E)-6-O-Methyl-Erythromycin Oxime, Bioorg. & Med. Chem.	

Date

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l				Application Number	10/615,010
	NFORMATIO	ON DISC	LOSURE	Filing Date	July 7, 2003
5	STATEMENT BY APPLICANT			First Named Inventor	Mladen MERCEP
				Art Unit	ТВА
	(Use as many sheets as necessary)			Examiner Name	ТВА
Sheet	2	of	3	Attorney Docket Number	03818/100L651-US1

		Lett., 8, 1998, 2427-2432
$C_{\mathcal{S}}$	14.	Lartey et al., "Synthesis of 4"-Deoxy Motilides: Identification of a Potent and Orally Active Prokinetic Drug Candidate, <i>J. Med. Chem.</i> , 38, 1998, 1793-1798
4,	15.	Kirst, H.A. et al., "34. Metabolism of macrolides," Bryskier, A. J. et al., Ed. Macrolides, Chemistry, Pharmacology and Clinical Use; Bryskier, Amette Blackwell: Paris, 1993; pp 485-491
Cy.	16.	Ma, Z. et al., "Discovery and Development of Ketolides as a New Generation of Macrolide Antimicrobial Agents," Current Medicinal Chemistry - Anti-Infective Agents, 1, 2002, 15-34
4.	17.	Pascual A. et al., "Uptake and intracellular activity of ketolide HMR 3647 in human phagocytic and non-phagocytic cells," Clin. Microbiol. Infect., 7, 2001, 65-69
G:	18.	Hand, W. L. et al., "Characteristics and mechanisms of azithromycin accumulation and efflux in human polymorphonuclear leukocytes," <i>Int. J. Antimicrob. Agents.</i> 18, 2001, 419-425
4	19.	Amsden, G. W., "Advanced-generation macrolides: tissue-directed antibiotics," Int. J. Antimicrob. Agents, 18, 2001, 11-15
ς,	20.	Johnson, J. D. et al., "Antibiotic uptake by alveolar macrophages," J. Lab. Clin. Med., 95, 1980, 429-439
4	21.	Wildfeuer, A. et al., "Uptake of Azithromycin by Various Cells and Its Intracellular Activity under In Vivo Conditions," Antimicrob. Agents Chemother., 40, 1996, 75-79
4	22.	Scomeaux, B. et al., "Intracellular Accumulation, Subcellular Distribution, and Efflux of Tilmicosin in Chicken Phagocytes," Poult. Sci., 77, 1998, 1510-1521
4	23.	Mtairag, E. M. et al., "Investigation of dirithromycin and erythromycylamine uptake by human neutrophils in vitro," J. Antimicrob. Chemother. 33, 1994, 523-536
Cy	24.	Anderson R. et al., "An in-vitro evaluation of the cellular uptake and intraphagocytic bioactivity of clarithromycin (A-56268, TE-031), a new macrolide antimicrobial agent," <i>J. Antimicrob. Chemother.</i> , 22, 1988, 923-933
ζγ.	25.	Tasaka, Y. et al., "Rokitamycin Uptake by Alveolar Macrophages," Jpn. J. Antibiot. 41, 1988, 836-840
ζ,	26.	Harf, R. et al., "Spiramycin uptake by alveolar macrophages," J. Antimicrob. Chemother., 22, 1988, 135-140
Sy	27.	Suzuki, T. et al., "General and facile method for determination of configuration of steroid-17-yl-methyl glycolates at C-20 based on kinetic examination," Chem. Soc., Perkin Trans. 1, 1998, 3831-3836
40	28.	McLean, H.M. et al., "Novel Fluorinated Antiinflammatory Steroid with Reduced Side Effects: Methyl 9α-Fluoroprednisolone-16-carboxylate," J. Pharm. Sci. 1994, 83, 476-480
4	29.	Little, R.J. et al., "Soft Drugs Based on Hydrocortisone: The Inactive Metabolite Approach and Its Application to Steroidal Antiinflammatory Agents." Pharm. Res., 16, 1999, 961-967
$\zeta_{\mathcal{D}}$	30.	Kertesz, D.J. et al., "Thiol Esters from Steroid 17β-Carboxylic Acids: Carboxylate Activation and Internal Participation by 17α-Acylates," <i>J. Org. Chem.</i> , 51, 1986, 2315-2328
4	31.	Phillipps, G. et al., "Synthesis and Structure - Activity Relationships in a Series of Antiinflammatory Corticosteroid Analogues, Halomethyl Androstane-17β-carbothioates and 17β-carboselenoates," J. Med. Chem. 37, 1994, 3717-3729
40	32.	Bright, G.M. et al., "Synthesis, In Vitro and In Vivo Activity of Novel 9-Deoxo-9a-AZA-9a-Homoerythromycin A Derivatives; A new Class of Macrolide Antibiotics, the Azalides" J. Antibiot., 41, 1998, 1029-1047

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		 Constacted	



PTO/SB/08a/b (06-03)

Approved for use through 07/31/2003. OMB 0651-0031

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				Art Unit	TBA .	
	(Use as many sheets as necessary)			Examiner Name	ТВА	
Sheet	3	of	3	Attorney Docket Number	03818/100L651-US1	

50	33.	Costa, A.M. et al., "Hybrids of macrolides and nucleobases or nucleosides," <i>Tetrahedron Letters</i> , 41, 2000, 3371-3375				
5,	34.	Luong et al., "Treatment options for Rheumatoid Arthritis: Celecoxib, Leflunomide, Etanerce and Infliximab," Ann. Pharmacother. 34, 2000, 743-760				
4	35.					
۲,	36.	Fournier, J., "COX-2 and Colon Cancer: Potential Targets for Chemoprevention," J. Cell Biochem. Suppl. 34, 2000, 97-102				
4	37.	Carswell, E.A., et al., "An endotoxin-induced serum factor that causes necrosis of tumors," Proc. Natl. Acad. Sci. USA 72, 1975, 3666-3670				
5/	38.	Elliot, M., et al., "Randomised double-blind comparison of chimeric monoclonal antibody to tumour necrosis factor α (cA2) versus placebo in rheumatoid arthritis," <i>Lancet</i> 344, 1994, 1105-1110				
4	39.	Mori, L., et al., "Attenuation of Collagen-Induced Arthritis in 55-kDa TNF Receptor Type 1 (TNFR1)-IgG1-Treated and TNFR1-Deficient Mice," J. Immunol. 157, 1996, 3178-3182				
4	40.					
4	41.					
ζ,	42.	Keffer, J., et al., "Transgenic mice expressing human tumour necrosis factor: a predictive genetic model of arthritis," EMBO J. 10, 1991, 4025-4031				
4	43.					
CV.	44.	Romo, D., et al., "Total Synthesis and Immunosuppressive Activity of (-)-Pateamine A and Related Compounds: Implementation of a β-Lactam-Based Macrocyclization," <i>J. Am. Chem. Soc.</i> 120, 1998, 12237-12254				

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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